

1 haven't been missed and so forth. But I'm actually
2 relatively struck that the adverse events are mostly
3 transient, and those that are not are ones that pretty much
4 could be expected for the disease.

5 I personally don't have any that just really
6 strikes out in my mind as being something that is of a major
7 concern, except to continue to look at it and monitor it.

8 I think No. 4 is pretty much the same question. I
9 think it's been answered. I think the consensus here is
10 that additional--if not necessarily studies, additional data
11 monitoring and collection is necessary. I think certainly
12 in a Phase 4 study, it can actually be incorporated into a
13 Phase 4 study without much more expense. So I'd like to go
14 ahead and move on to Question 5 if that's okay with the
15 panel.

16 Is there any--okay. Good. And it's actually a
17 little past 3:30 now--what time is it? A little past 2:40
18 now. Instead of taking a break, there's only two other
19 questions. I think if we can just get through these, it
20 will probably be better. Certainly some people who have to
21 catch an early flight, it would serve their needs also.

22 Okay. No. 5, Other issues related to the safety
23 or efficacy of the product? Any other issues? Dr. Fong,
24 can you start us off there?

25 DR. FONG: Nothing more than what I've said

1 already.

2 CHAIRMAN WILSON: Okay. Dr. Chew?

3 DR. CHEW: I don't have any more to add.

4 CHAIRMAN WILSON: Dr. Hannush?

5 DR. HANNUSH: Nothing more to add.

6 CHAIRMAN WILSON: Dr. Kilpatrick?

7 DR. KILPATRICK: No, nothing.

8 CHAIRMAN WILSON: Anybody want to add anything to
9 this?

10 [No response.]

11 CHAIRMAN WILSON: Okay. I also don't have
12 anything to add on this subject.

13 No. 6, are the data considered sufficient to
14 support an indication in patients with CMV retinitis who
15 have failed, or demonstrated intolerance to, at least
16 [questionable] other treatments for CMV retinitis?

17 I think the question here--Wiley, did you want us
18 to speculate about certain numbers of failed treatments or--

19 DR. KILPATRICK: May I ask Dr. Chambers also to
20 explain what--I just do not understand what is being asked
21 here.

22 CHAIRMAN WILSON: Yes.

23 DR. CHAMBERS: This was assuming that we got to
24 the point where the panel, the committee was going to--they
25 were recommending approval of the product. The question was

1 what indication that we then were dealing with, and the
2 question mark is there because it could be filled in with a
3 0, which essentially would mean primary therapy. It could
4 be filled in with a 1 or 2, meaning some type of level of
5 prior failure or intolerance to that. So I would both like
6 that number to be filled in, and I would like to see a hand
7 vote at this point for this question. That does not
8 necessarily mean you need to--the hand vote may end up being
9 some people saying a 0 is the most appropriate thing in
10 there, some people saying a 1, some people saying a 2. Just
11 what most fits in there, or some people saying no, it
12 shouldn't be approved at this point. So I think there are
13 probably at least four options to that.

14 CHAIRMAN WILSON: Okay. I think actually we
15 discussed some of this in the first question, but this would
16 be a way to formalize, I think, the response a little bit
17 better. So if we can do a hand vote, and I think the four
18 options would be: one, no approval; two, approval as--well,
19 0 would be there are other treatments that would be a
20 primary treatment; and then one other treatment or two other
21 treatments. Okay?

22 DR. HANNUSH: Can I possibly play the role of a
23 peacemaker here and is there a way to avoid that distinction
24 but put a lot of cautionary statements in the labeling?
25 This is a question of Dr. Chambers.

1 DR. CHAMBERS: Well, I guess I would turn that
2 back to--we would certainly be interested in comments that
3 anybody on the committee had of a way to properly convey to
4 people the uncertainty that certainly has been expressed by
5 members of this committee to the public should this product
6 be approved.

7 DR. HANNUSH: Well, my thoughts would be basically
8 saying that, you know, in the process--I don't know exactly
9 how labeling takes place, but in the process of approving
10 this drug, it was felt that it was important to bring it to
11 market, yet there were concerns about the sample data and
12 the size of the sample data, and, therefore, the conclusions
13 that were made were not based on sound statistical
14 principles, yet there was enough feeling that this should be
15 approved to make it available to the public. Or is that
16 really weak?

17 [Laughter.]

18 DR. DeLAP: I might chime in with just a couple of
19 other thoughts. I think what I personally am most
20 interested in is the up or down votes, yes or no, and then
21 knowing what the sentiments are of the individual members
22 when it comes to the 0, 1, or 2 kinds of issues. So perhaps
23 we could just have a hand showing for the primary question
24 of, yes, approve or, no, don't approve, and then we can hear
25 what the sentiments are, again, from the individual members,

1 whether they think it should be 0 or 1 or 2 plugged into
2 that box. I think that would suffice for us. Then we can
3 struggle with these issues of the exact labeling.

4 The labeling does have to be driven by science.
5 We recognize that there are social problems in our society
6 with the way medical care is delivered, and I think we're
7 troubled by that and we're troubled by the fact that
8 sometimes the way we label products is used as an excuse not
9 to treat people the way they should be treated. I think we
10 recognize that, and we're sympathetic to it, and we're
11 struggling with how best to deal with it.

12 In the end, I think we all just need the answers--
13 need the--there's the access questions and the answers that
14 I think we have to deal with here. One is that people need
15 to have access to the treatments that they need. People
16 also have to have the answers to the questions that need to
17 be answered so that they get treated right. And so we have
18 to insist that the research is done to really understand if
19 the products are used appropriately, say front-line. And,
20 again, we also have to be sympathetic to the other issues
21 that you raised so eloquently.

22 MR. FROST: I just want to say one thing. You
23 know, I've said publicly and I've actually written publicly,
24 Dr. DeLap, that I don't think the problems of a failed
25 health care system should be thrown on the doorstep of the

1 FDA. So I'm very sympathetic to the comments that you've
2 just made. I do think the labeling has to be driven by
3 science. But it can't be driven by science in a vacuum, and
4 so I think we all recognize that we are subject to the
5 environment in which we live, and that's the environment in
6 which we have to try to make these kinds of decisions.

7 I just want to say that in this particular
8 context, it's my opinion that the burden for making this
9 distinction really lies with the agency, because five other
10 products have been approved in this context in which no
11 distinction, as this, was made. So if there's a reason for
12 making such a distinction, I think the burden really lies
13 with the agency to make it clear why that distinction is
14 necessary and what function you really think it will serve.
15 Because I'm perfectly open to being convinced that it will
16 serve a useful function, but I've yet to hear what that is,
17 and I'm yet to be convinced in this context that this
18 product is special in that regard. And if so, I'd like to
19 know how.

20 DR. DeLAP May I just turn it back and say we just
21 want to know what you think of the science here, and we'll
22 work with your--

23 MR. FROST: Oh, well, we'll try to let you know
24 that.

25 DR. DeLAP: Okay.

1 [Laughter.]

2 CHAIRMAN WILSON: What I'd like to do then is have
3 two votes. The first vote is just a straightforward yes-no.
4 Yes for approval, no for non-approval. And then we'll go on
5 to a second vote, which would be filling in that blanks with
6 commentary. The first vote, please, will be all in favor--

7 MR. FROST: A point of information, Mr. Chairman.
8 Some of the members here I think are non-voting as
9 consultants, and maybe Ms. McGoodwin could make that--

10 MS. McGOODWIN: Yes. As long as the person is a
11 special government employee, which three of our four
12 consultants are, we've gotten them voting privileges.

13 MR. FROST: So I'm the only one not voting.

14 MS. McGOODWIN: Correct.

15 MR. FROST: Right. Well, I think everybody knows
16 how I feel.

17 [Laughter.]

18 CHAIRMAN WILSON: Of those that are eligible to
19 vote, please raise your hand if you vote for approval.

20 [A show of hands.]

21 CHAIRMAN WILSON: Non-approval?

22 [A show of hands.]

23 CHAIRMAN WILSON: Okay. Now, of the five, if we
24 can start with Dr. Mathews, your views on the second part of
25 this question, which is 1, 2, or 3 of the treatments, or 0

1 of the treatments; in other words, primary versus treatment
2 failures. And feel free to do whatever commentary related
3 to this.

4 DR. MATHEWS: Well, I am, as I said earlier,
5 uncomfortable with one or two drugs or, you know, having
6 failed local therapy versus systemic. I mean, there's a
7 whole bunch of different scenarios you could spin out.

8 My real concern is that this drug has not been
9 studied to the same degree in the same environment as the
10 previous agents. With all of the other agents that have
11 been studied, the issues about immune restoration were not
12 part of the scenario that was looked at. And now this drug
13 was caught in the middle of its development cycle in this
14 dilemma, and it's going to be the same situation for further
15 development plans. And I don't think we can just blow that
16 off and say, well, the crude effects of the treatment are
17 what drives everything. That's not convincing.

18 Therefore, I would not say one or two drugs that
19 failed. I think the labeling should make it very clear that
20 this agent is a new agent, has a lot of advantages in terms
21 of cross-resistance, potentially, but it has been studied
22 less intensively than other agents, and there is some data
23 to support its use in primary therapy as well as secondary
24 therapy, but the level of confidence in the magnitude of the
25 treatment effect I think has been overstated or potentially

1 overstatement by the sponsor. That's not to say that it's not
2 there, but I think it will shrink if the controls we've
3 talked about are rigorously employed.

4 CHAIRMAN WILSON: Dr. Hannush?

5 DR. HANNUSH: In answer to the agency's request
6 that we come up with a number, my vote is to place the
7 integer 1 in that category. My comment--and I think Dr.
8 Mathews eloquently answered Mr. Frost's concern--is to say
9 that the previous drugs did not have this restriction on
10 them, also the answer to--that is true, but the answer to
11 that is, if I recall correctly, when--I was only involved in
12 one of the approvals. The science was overwhelming at the
13 time. So, in fairness here, the science is limited. So if
14 Mr. Frost or others wanted to push the issue, the science
15 simply doesn't carry over the way I see it. Therefore, I
16 choose the number 1.

17 CHAIRMAN WILSON: Dr. Chew?

18 DR. CHEW: I would agree with Dr. Mathews in the
19 way of, I think, explaining the way that the trials have
20 been done and the way the trials have been conducted, in
21 particular this drug compared to others. But I really can't
22 give you a number based on the data we have on hand. I
23 think that's what Phase 4 is going to tell us, so I really
24 can't say that on the label say you're going to have to try
25 at least these number of drugs. I think it would be very

1 erroneous for us to sit here and say this is what we think
2 is going to happen. So I vote for 0.

3 CHAIRMAN WILSON: Dr. Fong?

4 DR. FONG: One.

5 CHAIRMAN WILSON: Let me see. You voted against,
6 so I don't think we need to--okay.

7 MS. COHEN: Can I just make a comment, if it gets
8 approved, about the labeling? I mean, the labeling has to
9 say that the science is limited and they don't have enough
10 experience. And I'm sitting here and I'm shaking my head,
11 and I'm hearing people say the science is limited, but
12 they've approved. So I don't understand our function.

13 DR. MATHEWS: You know, one of the things that I
14 think is very helpful about CMV retinitis is that if
15 somebody has regular follow-up, they're not going to get
16 into a lot of trouble with a competent ophthalmologist. In
17 the patients that we take care of who, for example, are
18 withdrawn from all CMV therapy, they are seen every month,
19 and it's fairly easy with a proper examination to tell
20 reactivation.

21 If this were an indication for CMV encephalitis
22 or, you know, colitis or something, there would be big
23 problems. But that fortunately is not what we're talking
24 about today.

25 CHAIRMAN WILSON: I think that the data is less

1 compelling for primary treatment than for re-treatment.
2 Nonetheless, I would agree that to put a restriction on it
3 might be counterproductive, and I think that more data is
4 necessary through other studies to take a look at this. So
5 I would probably put 0 and just continue to look at this--
6 the data is there. It's just not as compelling.

7 Any other final comments by any of the panelists,
8 any of the committee?

9 [No response.]

10 CHAIRMAN WILSON: Wiley, do you have any final
11 comments? Is there anything else you'd like for us to
12 consider?

13 DR. CHAMBERS: I do not at the time, except to
14 thank the committee very much for their careful
15 deliberations and discussion. We will take the advice that
16 we have heard under consideration, and we will make various
17 decisions based on it.

18 Again, I thank you very much for your input.

19 CHAIRMAN WILSON: The meeting is adjourned.

20 [Whereupon, at 2:53 p.m., the meeting was
21 adjourned.]

22 - - -

Ophthalmic Drugs Subcommittee of the
Dermatologic and Ophthalmic Drug Advisory Cmte

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